DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 11, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-21

Robert F. Doud, President
Custom Label Advance Nutrition
8258 South 192nd Street
Kent, Washington 98032

WARNING LETTER

Dear Mr. Doud:

On March 4, 5, 7, and 11, 2003, the Food and Drug Administration (FDA) conducted an inspection of your OTC repackaging and relabeling operation located at 8258 South 192nd Street, Kent, Washington. Our Investigators documented serious deviations from the Current Good Manufacturing Practice (CGMP) regulations (Title 21, Code of Federal Regulations, Part 210 and 211, which cause the drug products that are repackaged and relabeled by your firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

These deviations include, but are not limited to:

1. Failure to establish an adequate quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products. The responsibilities and procedures applicable to the quality control unit shall be in writing and shall be followed [21 CFR 211.22(a) and (d)].

    - Your firm does not review production records to determine compliance with all established, approved written procedures before a batch is released or distributed.

2. Failure to have adequate written SOPs describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed [21 CFR 211.125 (c) and (f)].

    - Your firm currently fails to follow established SOPs for review and approval of labels for finished drug products.

- Your firm currently does not reconcile the number of labels issued versus the number of labels actually used for drug product lots.

3. Failure to have written SOPs describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed; and failure to destroy obsolete and outdated labels [21 CFR 211.122(a) and (e)].

   - Your firm does not currently have adequate written SOPs for the relabeling operation.
   - Your firm currently uses unmarked envelopes with co-mingled labels as part of the relabeling operation.
   - Your firm currently fails to destroy obsolete and outdated labels from drug product lots, and instead maintains the outdated labels in customer files.

4. Failure to have adequate batch production and control records [21 CFR 211.188].

   - The head of quality control was unable to provide complete information relating to the production and control of each batch.

5. Failure to establish and follow adequate written procedures describing the handling of written and oral complaints regarding a drug product and to maintain a written record of each complaint [21 CFR 211.198(a) and (b)].

   - The firm currently fails to follow established procedures for handling product complaints. For example, the firm does not follow their procedure of using a Complaint Information Sheet to document complaints. The responsible person for handling complaints explained that she had forgotten that Complaint Information Sheets existed.

6. Failure to establish adequate written SOPs designed to assure that correct labels, labeling, and packaging materials are used for drug products. Failure to inspect packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations [21 CFR 211.130(e)].

   - Your firm currently fails to inspect packaging and labeling areas immediately before use to assure that all labeling materials not suitable for subsequent operations have been removed.

7. Failure to establish written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a)].

   - Your firm currently has no written SOPs for the repackaging of liquid products.

8. Failure to have building(s) used in the manufacture, processing, packing, or holding of a drug product, of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations. Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination [21 CFR 211.42(a) and (b)].

   - Released and non-released finished drug products are currently co-mingled in the same shipping area. Furthermore, reject materials are not properly stored as evidenced by the observation of an unopened carton of rejected bulk Vitamin B-1 50mg tablets found in the released materials area.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with the requirements of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

We received your April 3, 2003, response to the items listed on the FDA-483, which was issued to your firm on March 11, 2003. We find your response to be inadequate in that timeframes were not established to correct the significant regulatory violations documented during the inspection.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframes within which the corrections will be completed. Your response should be directed to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483